

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 10/674,653 Confirmation No.: 4786
Appellants : Marc E. Feinberg
Filed : September 30, 2003
For : TISSUE APPROXIMATION DEVICE
TC/Art Unit : 3731
Examiner : Melissa K. RYCKMAN
Docket No. : ETH-5092
Customer No.: 25570

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

APPEAL BRIEF UNDER 37 C.F.R. §41.37

Dear Sir:

Responsive to the Final Rejection mailed November 9, 2009, and the Advisory Action mailed April 2, 2010 as to the above-referenced application, a Notice of Appeal having been filed on April 9, 2010, Appellants submit the following Appeal Brief.

1. REAL PARTY IN INTEREST

The real party in interest is Ethicon, Inc. Route 22 West, Somerville, New Jersey 08876, as evidenced by the assignment recorded at reel 018748, frame 0824.

2. RELATED APPEALS AND INTERFERENCES

Appellants are unaware of any related appeals or interferences.

3. STATUS OF CLAIMS

Claims 3 through 6, 8, 14, 21, 22, and 27 through 50 remain pending in the present application. Claims 5, 6, 8, 38 through 42 and 46 through 48 stand finally rejected, the rejection of which is hereby appealed. Claims 3, 4, 14, 21, 22, 27-37, 43-45, 49 and 50 are withdrawn as being drawn to non-elected subject matter. Claims 1, 2, 7, 9 through 13, 15 through 20 and 23 through 26 have been canceled.

4. STATUS OF AMENDMENTS

The Advisory Action of April 2, 2010 indicates that the after final amendment filed February 12, 2010 will be entered for the purposes of appeal. The attached claims in the Claim Appendix (8) reflect the amendment.

5. SUMMARY OF THE CLAIMED SUBJECT MATTER

Under the provisions of 37 CFR 41.37(c)(1)(v), the following summary of claimed subject matter is made. The summary is in accordance with the rule since the rule does not require any particular format for this section of the Appeal Brief. Note also that the commentary to the rules provides "[a]ppellant may include any other information of record which will aid the Board in considering the subject matter of each independent claim." 69 FR 49976, Comment 53, third column, August 12, 2004.

Claim 8 is directed to a tissue approximation device comprising two elongate arms having proximal and distal ends, an attachment means to secure

the elongate arms to each other at one or more locations, adhesive pads movably connected on the ends of the elongate arms to anchor the tissue approximation device to the skin, and a locking means to lock the elongate arms in place relative to each other, wherein (i) the adhesive pads are spaced apart from the one or more locations of the attachment means in the direction of the elongate arms, and (ii) the tissue approximation device has an open and a closed position, and when in the closed position, the adhesive pads are parallel and non-contiguous to each other, where the adhesive pad has a first adhering surface and a second surface rotatably coupled to the distal end of each of the elongate arms by a ball and socket connector, wherein the second surface has one of a socket and a ball that communicates with the other one of a ball and a socket on the distal end of each of the elongate arms, and the adhesive pad is rotatable around the ball and socket connector about at least two axes.

The specification and drawings of this application describe and illustrate many embodiments of the tissue approximation device of claim 8. See, e.g., specification at page 4, line 9, through page 12, line 5, and Figures 1-12. Note that Figures 1-5 relate to a parallel forceps embodiment that has been withdrawn from consideration, in response to an election of species requirement, and that Figures 6-12 relate to the elected forceps species.

By way of example only, page 8, line 26 through page 9, line 20 of the specification states:

In the embodiment shown in Figure 6, the tissue approximation device is shown and designated generally by the numeral 100. The approximation forceps 100 have a flexible elongate arm 112, which is interconnected with and substantially similar to a flexible elongate arm 114. Elongate arms 112 and 114 each has a handle 112a and 114a and tong 112b and 114b and may be pivotally connected at attachment means, yoke 116. First and second elongate arms 112, 114 are pivoted in a scissors fashion. Handles 112a and 114a lie on the same plane and have at a proximal end thereof finger grips 118 and 120.

The tongs and adhesive pads interface may be designed to pivot multi directionally by means of a ball and socket mechanism shown in Figures 7 and 8 thus allowing the adhesive pads to conform to various anatomical structures such as a wrist or back. In addition this embodiment provides a means of rotating the adhesive pads with ball and socket 139, 141 to cooperate with yoke 116 allowing adhesive pads 130 and 140 to remain parallel to each other during wound approximation. The multi-directional pivoting motion can be limited by changing the distance from the center point of the ball 131 to surface 133 of adhesive pads 140 or 130 so rotation of the adhesive pads are more parallel to tongs 112b and 114b still allowing adhesive pads 130 and 140 to remain parallel to each other during wound approximation. The ball and socket 139, 141 design includes a slight interference fit allowing the alignment of adhesive pads 130 and 140 with the target anatomical structure and preventing the adhesive pads from flopping around during alignment and application. Preferably, adhesive pads 130, 140 remain parallel to each other and are non-contiguous such that the distance between the adhesive pads 130, 140 allows access to the wound for application of a permanent wound closure means.

As explained at page 11, lines 26-28, with the tissue approximation device of the present invention, a wound may be approximated without substantially everting the edge surfaces of the wound, during application of the wound closure means.

Claim 38 is directed to a tissue approximation device for application to a skin surface adjacent to a wound, comprising: a pair of arms, each arm having a longitudinal axis and opposed ends, wherein one end includes a handle and the other end includes a tong with a connector; an attachment mechanism coupled to each arm that movably couples the arms to each other so that a distance between each tong is selectively variable; an adhesive pad removably coupled to the connector of each tong, wherein each adhesive pad has an adhesive surface that extends in a plane generally parallel to the longitudinal axis of the respective tong, the adhesive surface having a high shear resistance for holding the skin surface and a low peel resistance for removal from the skin surface, and wherein the connectors support the adhesive pads to be positionable in a common plane

on opposed sides of the wound and conform to the skin surface adjacent to the wound; and a locking mechanism coupled to each arm to selectively lock the pair of arms in a fixed position relative to each other, wherein the connector is a rotatable connector that connects the adhesive pad to the tong to pivot at least about the longitudinal axis and an axis substantially perpendicular to the longitudinal axis and the rotatable connector is one of a ball and a socket and the adhesive pad includes the other of the ball and the socket, wherein the ball and socket are snap fit together in an interference fit.

The specification and drawings of this application describe and illustrate many embodiments of the tissue approximation device of claim 38. See, e.g., specification at page 4, line 9, through page 12, line 5, and Figures 1-12. Note that Figures 1-5 relate to a parallel forceps embodiment that has been withdrawn from consideration, in response to an election of species requirement, and that Figures 6-12 relate to the elected forceps species.

By way of example only, page 8, line 26 through page 9, line 20 of the specification states:

In the embodiment shown in Figure 6, the tissue approximation device is shown and designated generally by the numeral 100. The approximation forceps 100 have a flexible elongate arm 112, which is interconnected with and substantially similar to a flexible elongate arm 114. Elongate arms 112 and 114 each has a handle 112a and 114a and tong 112b and 114b and may be pivotally connected at attachment means, yoke 116. First and second elongate arms 112, 114 are pivoted in a scissors fashion. Handles 112a and 114a lie on the same plane and have at a proximal end thereof finger grips 118 and 120.

The tongs and adhesive pads interface may be designed to pivot multi directionally by means of a ball and socket mechanism shown in Figures 7 and 8 thus allowing the adhesive pads to conform to various anatomical structures such as a wrist or back. In addition this embodiment provides a means of rotating the adhesive pads with ball and socket 139, 141 to cooperate with yoke 116 allowing adhesive pads 130 and 140 to remain parallel to each other during

wound approximation. The multi-directional pivoting motion can be limited by changing the distance from the center point of the ball 131 to surface 133 of adhesive pads 140 or 130 so rotation of the adhesive pads are more parallel to tongs 112b and 114b still allowing adhesive pads 130 and 140 to remain parallel to each other during wound approximation. The ball and socket 139, 141 design includes a slight interference fit allowing the alignment of adhesive pads 130 and 140 with the target anatomical structure and preventing the adhesive pads from flopping around during alignment and application. Preferably, adhesive pads 130, 140 remain parallel to each other and are non-contiguous such that the distance between the adhesive pads 130, 140 allows access to the wound for application of a permanent wound closure means.

As explained at page 11, lines 26-28, with the tissue approximation device of the present invention, a wound may be approximated without substantially everting the edge surfaces of the wound, during application of the wound closure means.

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The Advisory Action of April 2, 2010 states that “[f]or purposes of appeal, the proposed amendment(s) ... will be entered ...” and that “[t]he examiner maintains the rejection dated 11/9/09 regarding the rejection of claims.” While not explicitly stating that the objections to the drawings and specification have been withdrawn, the Examiner has clearly stated that the rejection of all claims has been maintained, thus implicitly confirming the withdrawal of the aforementioned objections. Appellants thus believe that only the rejections relating to the pending claims are maintained, and are set forth below.

I. Claim 8 stands rejected under 35 U.S.C. §112, second paragraph as failing to have appropriate antecedent basis.

II. Claims 5, 6, 8, 38 through 42 and 46 through 48 stand rejected under 35 U.S.C. §103(a) as obvious over Taylor et al., U.S. Patent No. 6,394,951, in view of Coffey, U.S. Patent No. 2,003,629.

7. ARGUMENT

The Present Invention

The present invention is directed to a tissue approximation device. The claimed tissue approximation device includes two elongate arms having proximal and distal ends, an attachment means to secure the elongate arms to each other at one or more locations, adhesive pads movably connected on the ends of the elongate arms to anchor the tissue approximation device to the skin, and a locking means to lock the elongate arms in place relative to each other, wherein (i) the adhesive pads are spaced apart from the one or more locations of the attachment means in the direction of the elongate arms, and (ii) the tissue approximation device has an open and a closed position, and when in the closed position, the adhesive pads are parallel and non-contiguous to each other, where the adhesive pad has a first adhering surface and a second surface rotatably coupled to the distal end of each of the elongate arms by a ball and socket connector, wherein the second surface has one of a socket and a ball that communicates with the other one of a ball and a socket on the distal end of each of the elongate arms, and the adhesive pad is rotatable around the ball and socket connector about at least two axes.

The Relied-upon Reference

Taylor et al. propose methods and devices that a surgeon may use to stabilize a beating heart during a surgical procedure on the heart. As proposed, a stabilizing device is introduced through an opening in the chest and brought into contact with the beating heart. By contacting the heart with the device and

by exerting a stabilizing force on the device, the motion of the heart caused by the contraction of the heart muscles is effectively eliminated such that the heart is stabilized and the site of the surgery is said to move only minimally, if at all.

As proposed by Taylor et al., in separate steps, the surgeon contacts the heart with the stabilizing device, assesses the degree of movement of the anastomosis site, and exerts a force on the stabilizing device such that the contraction of the beating heart causes only minimal excess motion at the surgery site. By fixing the position of the stabilizing device in a configuration where the motion of the beating heart is effectively eliminated, the surgeon is able to stabilize the beating heart for the duration of the procedure. The stabilizing device may be attached to a rigid support or may be attached to a semi-rigid support which is rendered motionless mechanically, chemically, or by human intervention. In certain preferred embodiments, the stabilizing device is affixed to a semi-rigid support which is caused to become rigid, by any of a variety of techniques, such that the position of the stabilizing device becomes fixed by the support, and the heart remains substantially motionless for the duration of the procedure.

Taylor et al. describe Fig. 2 as having “snap-in member 16”, which has a post 18 formed on top of member 16, and a port 19 disposed in the body of contact member 1. Nowhere do Taylor et al. disclose or suggest that snap-in member 16 should be rotatable, or even movable.

Coffey proposes a terminal cleaning tool which is adapted to clean either a cylindrical or a conical internal surface or a cylindrical or conical external surface. The tool is adapted for cleaning storage battery terminals and their connectors in which it is desired to clean and to present a relatively smooth surface on the battery post to which is attached a connector with an electric cable lead from the battery. The batteries are usually made with a post having a slight taper forming a frustum of a cone and the connectors, which are usually split, have an internal

surface to correspond. The cleaning tool proposed is said to cleanse both of these surfaces.

The Rejections

I. Claim 8 stands rejected under 35 U.S.C. §112, second paragraph as failing to have appropriate antecedent basis.

At page 3 of the final Office Action, the Examiner indicates:

Claim 8 recites the limitation "the connector" in the last line of the claim. There is insufficient antecedent basis for this limitation in the claim. The examiner suggests changing "the connector" to "the ball and socket connector."

Appellants submit that their amendment under 37 C.F.R. 1.116, entered upon filing of the Notice of Appeal, moots this basis for rejection. Reversal of this rejection is courteously solicited in view thereof.

II. Claims 5, 6, 8, 38 through 42 and 46 through 48 stand rejected under 35 U.S.C. §103(a) as obvious over Taylor et al., U.S. Patent No. 6,394,951, in view of Coffey, U.S. Patent No. 2,003,629.

a. Separate argument of claim 8

i. Claim construction

In construing claim limitations it must be kept in mind that "as an initial matter, the PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the

written description contained in the applicant's specification." *In re Morris*, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997). [Emphasis added].

Here, claim 8 requires that the adhesive pads be movably connected on the ends of the elongate arms to anchor the tissue approximation device to the skin, and that the adhesive pad has a first adhering surface and a second surface rotatably coupled to the distal end of each of the elongate arms by a ball and socket connector. This is illustrated at page 4, line 23, through page 5, line 21, at page 9, line 23, through page 10, line 18, Figures 7, 8 and 12 and elsewhere within Appellants' specification.

iii. Analysis

The Examiner has committed legal and factual error in taking the following position with respect to independent claim 8:

Regarding Claim 8, Taylor teaches a tissue approximation device comprising two elongate arms (3), an attachment means (144) to secure the elongate arms to each other at one or more locations, adhesive pads (4, Column 14, proximate lines 1-37) movably connected (18, 19) on at least a portion of the elongate arms to anchor the tissue approximation device to the tissue (fig. 321a), and a locking means (181) to lock the elongate arms in place relative to each other, wherein (i) the adhesive pads are spaced apart from the one or more locations of the attachment means (144) in the direction of the elongate arms, and (ii) the tissue approximation device has an open (fig. 31b) and a closed position (fig. 31a), and when in the closed position, the adhesive pads are parallel and non-contiguous to each other (fig. 31a).

Taylor teaches the second surface coupled to the distal end of each of the elongate arms by a ball and socket connector (18 and 19, Fig. 2), wherein the second surface has one of a socket and a ball that communicates with the other one of a ball and a socket on the distal end of each of the elongate arms.

Taylor does not teach the first and second sockets being a rotatable connection, however Coffey teaches a rotatable connection between the elongate arms and the pad, and the

adhesive pad is rotatable around the connector about at least two axes (slight rotation is possible along two axes). It would have been obvious to one of ordinary skill in the art to use the rotatable connection of Coffey with the device of Taylor as this allows smooth action and aids in use of the jaws (page 1, ll. 47-55, page 2, col. 1, ll. 1-3). [Emphasis added].

Taylor's surgical instrument is designed for stabilizing a beating heart during coronary artery bypass graft surgery. Appellants respectfully traverse the Examiner's finding on the point that the adhesive pads are movably connected on at least a portion of the elongate arms, which is entirely unsupported by the language in Taylor et al. describing elements 18 and 19 (col. 14, lines 20-37). Taylor et al. describe Fig. 2 as having "snap-in member 16", which has a post 18 formed on top of member 16, and a port 19 disposed in the body of contact member 1. Nowhere do Taylor et al. disclose or suggest that snap-in member 16 should be movable, as suggested by the Examiner. The Examiner's finding is entirely unsupported by the cited reference.

The Examiner's position that Taylor's elements 18 and 19 would be movable relative to one another is unfounded, both in the Taylor et al. specification (as stated above), and from the view of the skilled artisan. In view of the extremely delicate nature of the surgery to be performed as set forth in Taylor et al., i.e. open heart surgery (col. 14, lines 38-40), the skilled artisan would not expect the Taylor et al. device to be designed or made such that unwanted movement could occur. Such movement would be very detrimental to the surgical procedure, where the utmost accuracy in positioning the Taylor et al. device would be required.

It is respectfully submitted that the Examiner's stated position that the device would be movable presumes a sloppy fit of the snap-in member and posts 18 within ports 19. As stated above, such an interpretation of the Taylor et al. device is unwarranted, not only by the literal language of the reference, but also by the expectations of the skilled artisan as to the requirements for devices used

in extremely exacting open heart surgery. Further, the skill in the arts of molding (if made of plastic) or machining is well-beyond the point of making a sloppy fitting snap-in connection, as presumably argued by the Examiner. As evidence, Appellants attach hereto an article entitled "Snap-Fit Joints for Plastics – A Design Guide" from Bayer Material Science, which illustrates the exacting nature of the design considerations for snap-fit joints.

In the Office Action of November 9, 2009, the Examiner recognizes that Taylor et al. fail to disclose or suggest first and second socket joints having a rotatable connection (Office Action, page 5).

The Examiner then points to Coffey and states:

Coffey teaches a rotatable connection between the elongate arms and the pad, and the adhesive pad is rotatable around the ball about at least two axes (slight rotation is possible along two axes). It would have been obvious to one of ordinary skill in the art to use the rotatable connection of Coffey with the device of Taylor as this allows smooth action and aids in the use of the jaws (page 1, ll. 47-55, page 2, col. 1, ll. 1-3). (Emphasis added).

Appellants traverse the Examiner's findings and conclusion for the reasons that follow.

First, it is respectfully submitted that Coffey is non-analogous art as to Taylor et al.

As noted hereinabove, Coffey discloses a battery terminal cleaning tool. In contrast, Taylor et al. disclose a surgical instrument for coronary artery bypass surgery. Appellants respectfully submit that the cited reference fields-of-use are so far removed, one from the other, that one skilled in the art (whichever art that might be) would not have looked to one reference to modify the other. To combine these references in the manner employed by the Examiner constitutes

clear legal error and reversal of this rejection is courteously solicited on this basis.

In response to Appellants' assertion of non-analogous art, the Examiner explains at page 7 of the Office Action of November 9, 2009:

The applicant argues Coffey is non-analogous art with Taylor, therefore a 103 rejection is improper. The examiner respectfully disagrees that the 103 rejection is improper. That is, it has been held that the determination that a reference is from a non-analogous art is twofold. First we decide if the reference is within the field of the inventor's endeavor. If it is not, we proceed to determine whether the reference is reasonably pertinent to the particular problem with which the inventor was involved. *In re Wood*, 202 USPQ 171, 174. In this case, Coffey teaches a rotatable connector in the field of approximation devices with elongate arms.

Appellants respectfully submit that the Examiner is improperly recasting the "field of Appellants' endeavor". At page 1 of the instant specification, Appellants state:

The present invention is directed to a tissue approximation device that is capable of maintaining approximation of a wound without substantial eversion of the edge surfaces of the wound and without requiring the physician or health care attendant to manually secure the device.

In contrast, Coffey discloses:

My invention relates to what I term an in and out terminal cleaning tool which is adapted to clean either a cylindrical or a conical internal surface or a cylindrical or conical external surface. The tool is especially adapted for cleaning storage battery terminals and their connectors... (page 1, column 1, lines 1-7).

Clearly, Coffey fails the first prong of the test for analogous art recited in *In re Wood, Id.* A battery terminal cleaner is certainly not “within the field of the inventor's endeavor”, which is a tissue approximation device.

Likewise, Coffey fails the second prong of the test for analogous art, i.e. “whether the reference is reasonably pertinent to the particular problem with which the inventor was involved”.

As set forth in the above-quoted portion of the present specification, the present device is configured to maintain “approximation of a wound without substantial eversion of the edge surfaces of the wound”. In contrast, the Coffey device “is adapted to clean either a cylindrical or a conical internal surface or a cylindrical or conical external surface”.

As may be appreciated, cleaning of a cylindrical or conical surface is entirely unrelated to tissue approximation. The Examiner's statement that “Coffey teaches a rotatable connector in the field of approximation devices with elongate arms” is entirely incorrect. Coffey fails to disclose tissue approximation whatsoever. In this case, by focusing only on the attachment portions of the Coffey device, the Examiner is guilty of impermissibly picking and choosing only so much of the prior art disclosure as supports her rejection, to the exclusion of the remaining reference teachings.

It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art. *In re Wesslau*, 147 USPQ 391, 393 (CCPA 1965).

A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d

1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984).

When considered as a whole, Coffey would not lead the skilled artisan to modify a tissue approximation device in any way. In view thereof, withdrawal of the rejection is requested on this basis alone.

Second, and quite importantly, Coffey fails to disclose adhesive pads whatsoever, despite the Examiner's indication to the contrary. Fig. 1 of Coffey illustrates the tool described therein. In particular the ball and socket mounted portions 32 and 33 are described as "circular jaws" and "their edges", respectively (page 1, col. 2, lines 41-47). One skilled in the art would certainly not interpret this disclosure to mean that items 32 and 33 are adhesive pads, or even the equivalents thereof.

Accordingly, a full and fair reading of Coffey would not have led the skilled artisan to modify the device of Taylor et al. *In re Wesslau, Id.*

Further, in view of the extremely delicate nature of the surgery to be performed as set forth in Taylor et al., i.e. open heart surgery, the skilled artisan would not have been motivated to look to Coffey, directed to an automotive tool, with any expectation of success in improving an apparatus for heart surgery (Taylor et al.). Additional axes of movement would be detrimental to the surgical procedure to be performed with the Taylor et al. device, where the utmost accuracy in positioning would be required. Note the Taylor et al. disclosure in Fig. 2, wherein the snap in members 16 are restricted in movement capability by the two posts 18 (col. 14, lines 20-28).

The Examiner's proposed modification of Taylor et al. runs afoul of the decision in *W.L. Gore & Associates, Inc. v. Garlock, Inc., Id.*, that is:

A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention.

In this case, the skilled artisan would not have been motivated to modify Taylor et al., which is directed to a tool for very fine and accurate positioning against heart tissue, in the manner of an automotive tool, which is configured for gross movements, and in this case for scraping-off corrosion from metal. Reversal of this rejection is courteously solicited on this basis.

Additionally, Appellants submit that modification of the Taylor et al. device in the manner suggested by Coffey would render the resulting device unsuitable for its intended purpose, as, as noted above, the additional axes of movement would be detrimental to the surgical procedure to be performed with the Taylor et al. device, where the utmost accuracy in positioning is required.

It is respectfully submitted that the Examiner has committed clear legal error in proposing the instant combination of references in an attempt to render Appellants' claimed invention prima facie obvious. In this regard, the Federal Circuit has held:

If the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984).

Reversal of this rejection is courteously solicited on these bases.

b. Separate argument of claims 5, 6 and 46-48

Solely for the purpose of this appeal, claims 5, 6 and 46-48 will not be separately argued and will stand or fall with claim 8.

Reversal of the rejection is courteously solicited.

c. Separate argument of claim 38

i. Claim construction

In construing claim limitations it must be kept in mind that "as an initial matter, the PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification." *In re Morris*, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997). [Emphasis added].

Here, claim 38 requires that the adhesive pad be removably coupled to the connector of each tong, the adhesive surface having a high shear resistance for holding the skin surface and a low peel resistance for removal from the skin surface, the connectors support the adhesive pads to be positionable in a common plane on opposed sides of the wound and conform to the skin surface adjacent to the wound, and the connector is a rotatable connector that connects the adhesive pad to the tong to pivot at least about the longitudinal axis and an axis substantially perpendicular to the longitudinal axis and the rotatable connector is one of a ball and a socket and the adhesive pad includes the other of the ball and the socket. This is illustrated at page 4, line 23, through page 5, line 21, at page 9, line 23, through page 10, line 18, Figures 7, 8 and 12 and elsewhere within Appellants' specification.

iii. Analysis

The Examiner has committed factual and legal error in taking the following position with respect to independent claim 38:

Regarding Claim 38, Taylor teaches a tissue approximation device capable of application to a skin surface adjacent to a wound comprising: a pair of arms (3), each arm having a longitudinal axis and opposed ends, wherein one end includes a handle (fig. 31 a) and the other end includes a tong (1) with a connector (19); and an attachment mechanism coupled to each arm (144) such that the distance between each tong is selectively variable; an adhesive pad (4) removably coupled to the connector of each tong (18) wherein each adhesive pad has an adhesive surface (4) that extends in a plane generally parallel to the longitudinal axis of the respective tong (fig. 2), the adhesive surface having a high shear resistance, and wherein the connectors support the adhesive pads to be positionable in a common plane on opposed sides of a wound; and a locking mechanism (151) coupled to each arm to selectively lock the pair of arms in a fixed position relative to each other.

Taylor does not teach the first and second sockets being having a rotatable connection, however Coffey teaches a rotatable connection between the elongate arms and the pad, and the adhesive pad is rotatable around the ball about at least two axes (slight rotation is possible along two axes). It would have been obvious to one of ordinary skill in the art to use the rotatable connection of Coffey with the device of Taylor as this allows smooth action and aids in use of the jaws (page 1, ll. 47-55, page 2, col. 1, ll. 1-3).

Claim 38 requires a rotatable connector that connects the adhesive pad to the tong to pivot at least about the longitudinal axis and an axis substantially perpendicular to the longitudinal axis. The rotatable connector is a ball and socket that are snap fit together in an interference fit. None of the embodiments of Taylor show this combination of features.

In the present Office Action, the Examiner recognizes that Taylor et al. fail to disclose or suggest first and second socket joints having a rotatable connection (Office Action, page 5).

The Examiner then points to Coffey and states:

Coffey teaches a rotatable connection between the elongate arms and the pad, and the adhesive pad is rotatable around the ball about at least two axes (slight rotation is possible along two axes). It would have been obvious to one of ordinary skill in the art to use the rotatable connection of Coffey with the device of Taylor as this allows smooth action and aids in the use of the jaws (page 1, ll. 47-55, page 2, col. 1, ll. 1-3). (Emphasis added).

Applicants traverse the Examiner's findings and conclusion for several reasons.

As asserted above, it is respectfully submitted that Coffey is non-analogous art as to Taylor et al. Coffey discloses a battery terminal cleaning tool. In contrast, Taylor et al. disclose a surgical instrument for coronary artery bypass surgery. Applicants respectfully submit that the cited reference fields-of-use are so far removed, one from the other, that one skilled in the art (whichever art that might be) would not have looked to one reference to modify the other. To combine these references in the manner employed by the Examiner constitutes clear legal error and reversal of this rejection is courteously solicited on this basis.

In response to Applicants' assertion of non-analogous art, the Examiner explains:

Applicant's arguments filed 6/15/09 have been fully considered but they are not persuasive. The applicant argues Coffey is non-analogous art with Taylor, therefore a 103 rejection is improper. The examiner respectfully disagrees that the 103 rejection is improper. That is, it has been held that the determination that a

reference is from a non-analogous art is twofold. First we decide if the reference is within the field of the inventor's endeavor. If it is not, we proceed to determine whether the reference is reasonably pertinent to the particular problem with which the inventor was involved. *In re Wood*, 202 USPQ 171, 174. In this case, Coffey teaches a rotatable connector in the field of approximation devices with elongate arms.

Applicants respectfully submit that the Examiner is improperly recasting the "field of Applicants' endeavor". At page 1 of the specification, Applicants state:

The present invention is directed to a tissue approximation device that is capable of maintaining approximation of a wound without substantial eversion of the edge surfaces of the wound and without requiring the physician or health care attendant to manually secure the device.

In contrast, Coffey discloses:

My invention relates to what I term an in and out terminal cleaning tool which is adapted to clean either a cylindrical or a conical internal surface or a cylindrical or conical external surface. The tool is especially adapted for cleaning storage battery terminals and their connectors... (page 1, column 1, lines 1-7).

Clearly, Coffey fails the first prong of the test for analogous art recited in *In re Wood, Id.* A battery terminal cleaner is certainly not "within the field of the inventor's endeavor", which is a tissue approximation device. Likewise, Coffey fails the second prong of the test for analogous art, i.e. "whether the reference is reasonably pertinent to the particular problem with which the inventor was involved".

As set forth in the above-quoted portion of the present specification, the present device is configured to maintain "approximation of a wound without substantial eversion of the edge surfaces of the wound". In contrast, the Coffey

device “is adapted to clean either a cylindrical or a conical internal surface or a cylindrical or conical external surface”.

Cleaning of a cylindrical or conical surface is entirely unrelated to tissue approximation. The Examiner’s statement that “Coffey teaches a rotatable connector in the field of approximation devices with elongate arms” is entirely incorrect. Coffey fails to disclose tissue approximation whatsoever. In this case, by focusing only on the attachment portions of the Coffey device, the Examiner is guilty of impermissibly picking and choosing only so much of the prior art disclosure as supports her rejection, to the exclusion of the remaining reference teachings.

It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art. *In re Wesslau*, 147 USPQ 391, 393 (CCPA 1965).

A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984).

When considered as a whole, Coffey would not lead the skilled artisan to modify a tissue approximation device in any way. Reversal of this rejection is courteously solicited on this basis alone.

Second, Coffey fails to disclose adhesive pads whatsoever, despite the Examiner’s indication to the contrary. Fig. 1 of Coffey illustrates the tool described therein. In particular the ball and socket mounted portions 32 and 33 are described as “circular jaws” and “their edges”, respectively (page 1, col. 2, lines 41-47). One skilled in the art would certainly not interpret this disclosure to mean that items 32 and 33 are adhesive pads, or even the equivalents thereof.

Accordingly, a full and fair reading of Coffey would not have led the skilled artisan to modify the device of Taylor et al. *In re Wesslau, Id.*

Further, in view of the extremely delicate nature of the surgery to be performed as set forth in Taylor et al., i.e. open heart surgery, the skilled artisan would not have been motivated to look to Coffey, directed to an automotive tool, with any expectation of success in improving an apparatus for heart surgery (Taylor et al.). Additional axes of movement would likely be detrimental to the surgical procedure to be performed with the Taylor et al. device, where the utmost accuracy in positioning would be required. Note the Taylor et al. disclosure in Fig. 2, wherein the snap in members 16 are restricted in movement capability by the two posts 18 (col. 14, lines 20-28).

The Examiner's proposed modification of Taylor et al. runs afoul of the decision in *W.L. Gore & Associates, Inc. v. Garlock, Inc., Id.*, that is:

A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention.

In this case, the skilled artisan would not have been motivated to modify Taylor et al., which is directed to a tool for very fine and accurate positioning against heart tissue, in the manner of an automotive tool, which is configured for gross movements, and in this case for scraping-off corrosion from metal.

Reversal of this rejection is courteously solicited on these bases.

d. Separate argument of claims 39-42

Solely for the purpose of this appeal, claims 39-42 will not be separately argued and will stand or fall with claim 38.

Reversal of the rejection is courteously solicited.

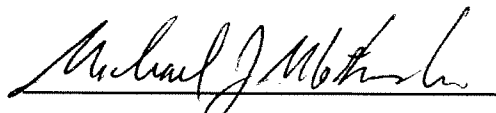
Summary

Even assuming that the relied upon references are legally combinable in the manner suggested by the Examiner, which Appellants have strenuously asserted they are not, when the claims are properly construed, it is seen that Appellants' tissue approximation device is nevertheless patentable over such a combination. However, as noted herein, the skilled artisan would not have been motivated to modify Taylor et al., directed to a tool for very fine and accurate positioning against heart tissue, in the manner of an automotive tool, configured for gross movements, and in this case for scraping corrosion from metal battery terminals.

The Board of Appeals is respectfully requested to remand this application to the Examiner with a direction to allow the claims.

Respectfully submitted,

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8. CLAIMS APPENDIX

5. The tissue approximation device of claim 8, where the elongate arms form a pair of forceps, the attachment means is a yoke on the forceps, and the locking means is a ratchet mechanism on the forceps.

6. The tissue approximation device of claim 5, where the distance between the elongate arms is adjustable by means of a ratchet mechanism.

8. A tissue approximation device comprising two elongate arms having proximal and distal ends, an attachment means to secure the elongate arms to each other at one or more locations, adhesive pads movably connected on the ends of the elongate arms to anchor the tissue approximation device to the skin, and a locking means to lock the elongate arms in place relative to each other, wherein (i) the adhesive pads are spaced apart from the one or more locations of the attachment means in the direction of the elongate arms, and (ii) the tissue approximation device has an open and a closed position, and when in the closed position, the adhesive pads are parallel and non-contiguous to each other, where the adhesive pad has a first adhering surface and a second surface rotatably coupled to the distal end of each of the elongate arms by a ball and socket connector, wherein the second surface has one of a socket and a ball that communicates with the other one of a ball and a socket on the distal end of each of the elongate arms, and the adhesive pad is rotatable around the ball and socket connector about at least two axes.

38. A tissue approximation device for application to a skin surface adjacent to a wound, comprising:

a pair of arms, each arm having a longitudinal axis and opposed ends, wherein one end includes a handle and the other end includes a tong with a connector;

an attachment mechanism coupled to each arm that movably couples the arms to each other so that a distance between each tong is selectively variable;

an adhesive pad removably coupled to the connector of each tong, wherein each adhesive pad has an adhesive surface that extends in a plane generally parallel to the longitudinal axis of the respective tong, the adhesive surface having a high shear resistance for holding the skin surface and a low peel resistance for removal from the skin surface, and wherein the connectors support the adhesive pads to be positionable in a common plane on opposed sides of the wound and conform to the skin surface adjacent to the wound; and

a locking mechanism coupled to each arm to selectively lock the pair of arms in a fixed position relative to each other,

wherein the connector is a rotatable connector that connects the adhesive pad to the tong to pivot at least about the longitudinal axis and an axis substantially perpendicular to the longitudinal axis and the rotatable connector is one of a ball and a socket and the adhesive pad includes the other of the ball and the socket, wherein the ball and socket are snap fit together in an interference fit.

39. The device of claim 38, wherein the arms are connected in a scissors configuration.

40. The device of claim 38, wherein the adhesive pad includes serrations that provide flexibility to the adhesive surface.

41. The device of claim 38, wherein the locking mechanism includes a ratchet.

42. The device of claim 38, wherein the arms are made of a resilient material.

46. The device of claim 8, wherein the second surface has the socket and the distal end has the ball.

47. The device of claim 8, wherein the second surface has the ball and the distal end has the socket.

48. The device of claim 8, wherein the second surface and the distal end of the elongate arm connect in a snap fit manner.

9. EVIDENCE APPENDIX

"Snap-Fit Joints for Plastics – A Design Guide" from Bayer Material Science.

10. RELATED PROCEEDINGS APPENDIX

None